

REMARKS

Upon entry of this amendment, claims 1-7, 9-29, 133-138, 140-150 will be pending in this application, of which claims 1-29, 133, 144, 148, 149 and 150 are being amended, claims 8, 30-132 and 139 are being canceled, and claims 151-207 are being added.

Applicant affirms election of the claims of Group I, as defined by the Examiner, namely claims 1-29 and 133-150, and the species of claim 10 (surfactant comprising a lipid), without traverse.

Applicant is canceling the non-elected claims 8, 30-132, and 139, without prejudice or disclaimer.

Claims 1-29 are being amended to remove the word "stable" from the preamble to cosmetically improve the claim language. Claim 27 and 149 and the Specification are being corrected to correct the spelling of the word anticholinergics; and claims 13 and 144 and the Specification are being corrected to correct the spelling of the word dioleoylphosphatidylcholine. Added claims 151 – 207 are supported by original claims 1- 29 and by the Specification. Thus, the amendments and added claims are fully supported by the originally filed specification and original claims and add no new matter. Entry of the amendments and reconsideration of the present case is respectfully requested.

Drawings

As requested by the Examiner, Applicant will resubmit clearer version of the photographs of Figures 1-3 as soon as these are available.

Specification

The Specification is being amended to correct the spelling of the word dioleoylphosphatidylcholine.

The Specification is also being amended to capitalize trademarks in the text and to recite the generic versions of the trademarks in the text.

The subject matter incorporated by reference will be reviewed by the inventors and a Supplemental Amendment filed as needed to enter any material considered desirable into the application.

Rejection Under 35 U.S.C. 112

Claim 1:

The word "substantially" is being deleted from claim 1 with the understanding that the word permeation means that a liquid permeates into at least some, but not necessarily all of, the pores, perforations, or holes in the particles; thus, the word "substantially" before permeation is unnecessary. As stated in the Specification, "[i]n this regard, the perforated microstructures preferably comprise pores, voids, hollows, defects or other interstitial spaces that allow the fluid suspension medium to freely permeate or perfuse the particulate boundary." (Emphasis added, page 11, lines 19-21.) Also, the word "permeate" is defined as "to diffuse through or penetrate something" or "to pass through the pores or interstices of", Merriam-Webster's Medical Dictionary, Merriam-Webster Inc., 2002. Thus, the word "permeate" means penetration into perforations, but does not mean that all perforations have to be permeated, or that any one perforation has to be permeated.

Further, since an unnecessary or redundant word is being deleted from the claim, the proposed amendment only makes express, a recitation of a feature that was already inherent in the original claim, and thus, is not a narrowing of the scope of

NK.56.11
Application No: 10/644,265
Page 24 of 26

the properly construed claim. TurboCare v. General Electric Co., 264 F.3d 1111 (Fed. Cir. 2001); Bose Corp. v. JBL, Inc., 274 F.3d 1354 (Fed. Cir. 2001); and Interactive Pictures Corp. v. Infinite Pictures, Inc., 274 F.3d 1371 (Fed. Cir. 2001). Deletion of the word "substantially" is a purely cosmetic change that does not affect the scope of the claim; and thus, the scope of the doctrine of equivalents applied to the claim should not be limited under the rules of Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 2002 Lexis 3818 (May 28, 2002).

Claim 26:

The word "substantially" is not being deleted from claim 26, because it is needed to signify that the density of the suspended particles permeated with the suspension medium is similar to, but not identical with, or "substantially matches" that of the suspension medium. Applicant respectfully submits that "substantially" is commonly used and accepted language in patent claims to signify a close but not identical match.

Claims 21-23 and 148:

Claims 21-23 and 148 are being amended to recite that the "perforated microstructures" comprise a mean geometric diameter. This is also a cosmetic amendment that does not narrow the scope of equivalents of the claim, since the amendments only make express, a recitation of a feature, namely the diameter of the perforated microstructure recited in the parent claim, which was already inherent in the perforated microstructure particle.

Rejection Under 35 U.S.C. 103(a)

The Examiner rejected claims 133-138, 141, 143 and 144 under 35 U.S.C. 103(a) as being unpatentable over Platz et al. (WO 91/16038).

The Examiner states that Platz et al. teaches "aerosol formulations of biologically active solid polypeptide microparticles" that may be "prepared as aerosol

suspensions in a pressurized metered-dose inhaler." The Examiner further states that "Platz teaches that to improve the dispersion in liquid suspensions and to inhibit aggregation, some kind of surfactant is preferably added to the milled polypeptide powder", and that "the surfactant includes phospholipids, phosphatidylcholine and natural lecithins...."

Applicant respectfully submits that Platz et al. does not teach claim 133, as amended, which reads on a respiratory dispersion for the pulmonary delivery of one or more bioactive agents, the dispersion comprising a suspension medium having dispersed therein a plurality of perforated microparticles comprising greater than about 20% w/w surfactant and at least one bioactive agent wherein said suspension medium comprises at least one propellant and permeates said perforated microstructures. For example, Platz et al. does not teach a respiratory dispersion comprising a plurality of perforated microparticles. Nor does Platz et al. teach that the respiratory dispersion comprises a suspension medium that permeates the perforated microstructures. Instead Platz et al. teaches "solid micronized particles" (Abstract). Thus, claim 133 and the claims dependent therefrom are now allowable over Platz et al.

Double Patenting

1. The Examiner rejected claims 1-7, 9-29, 133-138 and 140-150 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 9-29 and 72-87 of U.S. Patent No. 6,309,623.

Upon allowance of the present application, Applicant will file a Terminal Disclaimer over U.S. Patent No. 6,309,623 to overcome this rejection.

The term "substantially" has been deleted from claim 1. However, the meaning of the term "permeates" is now clarified herein, and thus, not limited to 30% as suggested by the Examiner.

NK.58.11
Application No: 10/644,265
Page 26 of 26

2. The Examiner further rejected claims 1, 133-134, 136, 138, 143, 144 and 147-150 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5-6, 8-11, 13, 14, and 16 of U.S. Patent No. 6,630,169.

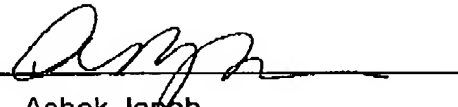
Upon allowance of the present application, Applicant will file a Terminal Disclaimer over U.S. Patent No. 6,630,169 to overcome this rejection.

CONCLUSION

The above-discussed amendments and remarks are believed to place the present application in condition for allowance. Should the Examiner have any questions regarding the above remarks, the Examiner is requested to telephone Applicant's representative at the number listed below.

Respectfully submitted,
JANAH & ASSOCIATES, P.C.

Date: 2/7/2006

By: 
Ashok Janah
Reg. No. 37,487

Please direct all telephone calls to: Ashok K. Janah at (415) 538-1555.

Please send correspondence to:

Michael Einschlag
Nektar Therapeutics
150 Industrial Road
San Carlos, CA 94070.